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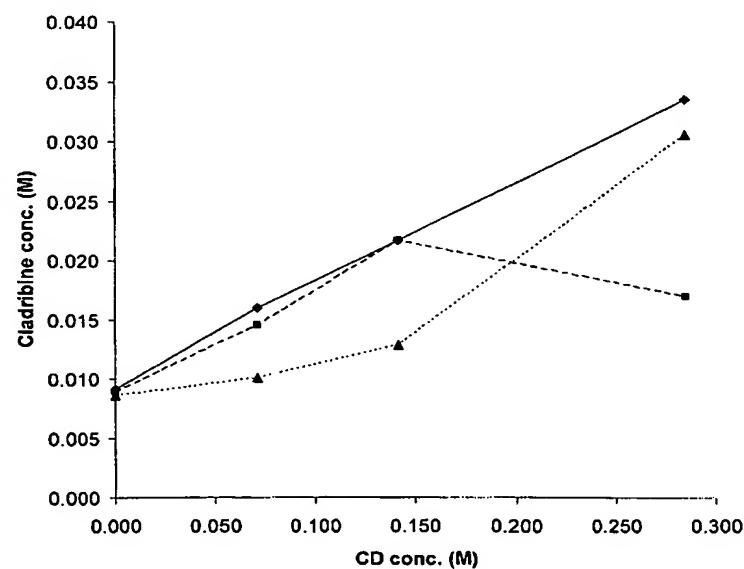
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[Continued on next page]

(54) Title: CLADRIBINE FORMULATIONS FOR IMPROVED ORAL AND TRANSMUCOSAL DELIVERY



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(57) Abstract: Provided are compositions of cladribine and cyclodextrin which are especially suited for the oral and buccal administration of cladribine.



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# INTERNATIONAL SEARCH REPORT

International Application No  
T/US2004/009384

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K9/20 A61K47/48 A61K31/52 A61K9/00			
According to International Patent Classification (IPC) or to both national classification and IPC			
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61K			
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched			
Electronic data base consulted during the International search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, EMBASE, CHEM ABS Data			
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
A	US 6 194 395 B1 (NAEFF RAINER ET AL) 27 February 2001 (2001-02-27) cited in the application the whole document -----	1-61	
A	US 4 727 064 A (PITHA JOSEF) 23 February 1988 (1988-02-23) the whole document -----	1-61	
A	US 4 870 060 A (MUELLER BERND W W) 26 September 1989 (1989-09-26) the whole document -----	1-61	
<input type="checkbox"/> Further documents are listed in the continuation of box C.		<input checked="" type="checkbox"/> Patent family members are listed in annex.	
* Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the International filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed			
*T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family			
Date of the actual completion of the International search  2 December 2004		Date of mailing of the International search report  10/12/2004	
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  Toulacis, C	

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2004/009384

### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:  
Although claims 13-37 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/US2004/009384

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 6194395	B1	27-02-2001		NONE
US 4727064	A	23-02-1988	US 4596795 A	24-06-1986
US 4870060	A	26-09-1989	AT 124055 T AT 159954 T AU 583599 B2 AU 5476086 A CA 1300130 C CY 1918 A DE 3650336 D1 DE 3650655 D1 DE 3650655 T2 DK 121486 A DK 200201960 A EP 0197571 A2 EP 0636634 A1 ES 8705899 A1 FI 861064 A ,B, FI 86507 B GR 860685 A1 HK 131896 A HU 42514 A2 HU 206381 B IE 66673 B1 IE 80908 B1 IE 950700 L JP 2562809 B2 JP 61275301 A KR 9307386 B1 NO 860971 A ,B, NZ 215350 A PT 82186 A ,B SG 48788 A1 US 4764604 A ZA 8601930 A	15-07-1995 15-11-1997 04-05-1989 16-10-1986 05-05-1992 07-03-1997 27-07-1995 11-12-1997 12-03-1998 16-09-1986 10-02-2003 15-10-1986 01-02-1995 01-08-1987 16-09-1986 29-05-1992 11-07-1986 26-07-1996 28-07-1987 28-10-1992 24-01-1996 16-06-1999 15-09-1986 11-12-1996 05-12-1986 09-08-1993 16-09-1986 29-03-1989 01-04-1986 18-05-1998 16-08-1988 28-10-1987